DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
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9-1473d

June 29, 2001

VIA FEDERAL EXPRESS

Galen A. Merrill
Director, Quality Assurance- Compliance
Aventis Bio-Services
180 A. Market Place Blvd.
Knoxville, TN 37922

WARNING LETTER
(01-ATL-57)

Dear Mr. Merrill:

During an inspection of your facility, Seramed, Inc. d.b.a. Aventis Bio Services, 112 West Stone Avenue, Greenville, South Carolina, conducted on 4/19-20 & 5/30-6/6/01, our investigator documented violations of Sections 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to maintain and/or follow adequate written standard operating procedures (SOPs) to include all steps to be followed in the collection, processing, storage and distribution of blood and blood products [21 CFR 606.100 (b)] in that:

   a) Donor record file/documentation review revealed sixteen instances of overbleeds. Two of the donors were overdrawn on repeated occasions. No investigations were conducted to determine cause (s) of these overbleeds. Also, no corrective action was implemented as a result of these overbleeds.

   b) There are no written procedures and controls in place to assure that the manual permanently deferred donor files are checked when determining the suitability of new donors. Not all permanently deferred donors are included in your [redacted] computer system. In order to verify that a new donor is not permanently deferred, screening personnel must access the manual file. However, there are no written procedures instructing employees to check the manual file.

   c) Failure to conduct quality control and preventative maintenance on the line sensors and fluid sensors on all of the [redacted] machines at your facility. The user's manual recommends weekly maintenance of the fluid and line sensors. Maintenance of these sensors has not been done.

2. Failure of personnel to have a thorough understanding of the procedures or control operations they perform, and/or the necessary training or experience in their respective functions [21 CFR 606.20(b)], in that:

a) Two donors who experienced red blood cell loss and/or whole blood loss were not deferred. Multiple personnel were involved in the review of these donor records and determination of donor suitability, however these donors were allowed to donate. No corrective or preventative action was taken.

b) A donor was allowed to donate without undergoing a physical examination. The disposition of units collected from this donor was not documented.

c) An employee made at least 3 significant errors involving machine set-up operations. A fourth error by the same employee was noted in which the anticoagulant and saline were switched on the [redacted] machine.

d) Employee training on the use of the new [redacted] computer system, which is used in donor screening and product processing, was not complete. Employees were not very familiar with this computer system. Additionally, the center director had not received any training on this computer system even though he retains a high security level for data entered on this computer system.

3. Failure to maintain complete and accurate records [21 CFR 606.160] in that:

a) The validation and installation records for the [redacted] computer system were incomplete. Installation of this system was performed on 11/17/2000, however the validation study was not formally approved until 4/19/2001. The validation study was signed off even though incomplete testing was noted in the following areas: [redacted]

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps that you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your reply should be directed to Serene A. Kimel, Compliance Officer, at the address in the letterhead.

Sincerely yours,

Barbara G. Wood for

Ballard Graham, Director
Atlanta District

CC: Mr. Richard A. Martin
Center Director
Aventis Bio-Services
112 West Stone Avenue
Greenville, SC 29609